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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,755

09/10/2003

Richard A. Dixon

NBLE:007US

4103

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02/03/2009

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EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

02/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/659,755	<b>Applicant(s)</b> DIXON ET AL.	
	<b>Examiner</b> RUSSELL KALLIS	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-50 is/are pending in the application.
- 4a) Of the above claim(s) 36-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-35 and 46-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/2008 has been entered.

Applicants' request for withdrawal of finality is based upon the belief that the final office action added a rejection not based upon the claim amendments. However, Applicant has not stated any specifics. Nonetheless, the new rejection under 103(a) included art previously used in the rejection under 102(b), now withdrawn; and art already of record filed in Applicants' IDS. Further, the claims have been, and still are rejected under 103(a). Furthermore, Applicant is required to file an RCE, with petition in order to revive an abandoned Application.

***Claim Objections***

Claims 3 and 7 fail to further limit Claim 4.

***Claim Rejections - 35 USC § 103***

Claims 2-35 and 46-50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yu O. *et al.* Plant Physiology, 2000; Vol. 124, pp. 781-793 in view of Wisman *et al.* PNAS, Oct. 1998, Vol. 95, pp. 12432-12437 and in further view of Applicant's disclosure of the state of the prior art. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/21/2008. Applicant's arguments filed 10/28/2008 have been considered but are not deemed persuasive.

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Applicant asserts that neither Yu nor Wisman provide further elucidation into the relevant controls of the phenyl propanoid pathway (response page 11) is not persuasive because both Yu and Wisman provide sufficient evidence for one of ordinary skill to produce isoflavonoids in plants transformed with isoflavonoid synthase with a reasonable expectation of success.

Applicants' assertions that Phenyl Ammonia Lyase (PAL) or Caffeic acid-3-O-methyltransferase when overexpressed leads to unpredictable results (response page 11) is not persuasive because none of those are sufficient to overcome the positive results of Yu and Wisman. In addition, PAL is an enzyme expressed upstream of the enzymes of the instant claims and can not be used for any reasonable comparison. Likewise, Caffeic acid-3-O-methyltransferase is a component of lignin biosynthesis and is not directly related to the enzymes of the instant claims as well as those portions of alkaloid biosynthesis referenced on page 12 of Applicants' arguments.

Applicants' assertions that metabolic channeling and competition for substrate are complicating factors in genetic engineering of plant natural products (response page 12) are not persuasive arguments for unpredictability in producing isoflavonoids in plants because as presented supra and in previous office actions, isoflavonoids have already been produced in non-isoflavonoid producing plants i.e. non-leguminous plants and the down regulation of flavanone 3-hydroxylase did not produce any unexpected results that would render unpredictable producing isoflavonoids in transformed plants. Moreover, Applicants' arguments are contrary to the evidence in the IDS filed 12/18/2006 that teaches the enabling aspects of overexpression of the phenylpropanoid pathway in engineering isoflavonoids in transgenic plants see reference C34 abstract (Yu *et al.* Phytochemistry 2003, Vol. 63; pp. 753-763).

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Claims 2-35 and 46-50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,189,895 (McGonigle, B. and Odell, J.) with the effective filing date of June 13, 2002 (60/388,280) in view WO 00/44909 of published August 3<sup>rd</sup>, 2000; and in further view of Applicant's disclosure of the state of the prior art. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/30/2007 and 4/21/2008. Applicant's arguments filed 10/28/2008 have been considered but are not deemed persuasive.

Applicants' assertion that the '895 Patent can not be used as prior art against the instant claims is not persuasive because the evidence submitted in the affidavit does not address all the limitations rejected under 103(a), namely the upregulation of chalcone isomerase and synthase that are taught by the '895 Patent; and thus contrary to Applicants' assertion, they had not reduced to practice the instant invention as broadly claimed.

Applicants' arguments in the response on pages 15-16 that the '895 Patent did not teach increased activity of isoflavanone synthase in soybean transformed with C1 and R transcription factors from maize, one of ordinary skill could easily conclude that since transformation with C1 and R increased the total amount of isoflavones in the transformed plants by four fold the activity of the endogenous isoflavone synthase was upregulated as measured by the increase in isoflavonoid product formed. One of ordinary skill in the art would have been led by the '895 Patent to further experimentation to optimize the flux through the isoflavonoid pathway by means of transforming a plant with an isoflavone synthase known to be the required factor for biochemical synthesis of isoflavonoids as taught by WO 00/44909.

No claim is allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUSSELL KALLIS whose telephone number is (571)272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/  
Primary Examiner, Art Unit 1638  
February 1, 2009

<b>Application Number</b> 	<b>Application/Control No.</b>	<b>Applicant(s)/Patent under Reexamination</b>	
	10/659,755	DIXON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	RUSSELL KALLIS	1638	